4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Request for Nominations for Individuals and Consumer Organizations for Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any consumer organizations interested in participating in the selection of voting and/or nonvoting consumer representatives to serve on its advisory committees or panels notify FDA in writing. FDA is also requesting nominations for voting and/or nonvoting consumer representatives to serve on advisory committees and/or panels for which vacancies currently exist or are expected to occur in the near future. Nominees recommended to serve as a voting or nonvoting consumer representative may be self-nominated or may be nominated by a consumer organization.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests on an FDA advisory committee or panel may send a letter or email stating that interest to FDA (see

ADDRESSES) by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], for vacancies listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA (see ADDRESSES) by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Nominations will be accepted for current vacancies and for those that will or may occur through March 31, 2016.

ADDRESSES: All statements of interest from consumer organizations interested in participating in the selection process and consumer representative nominations should be submitted electronically to kimberly.hamilton@fda.hhs.gov, by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993-0002, or by FAX: 301-847-8640.

Consumer Representative nominations should be submitted electronically by logging into the FDA Advisory Committee Membership Nomination Portal: https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm, by mail to Advisory Committee Oversight and Management Staff, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993-0002, or by FAX: 301-847-8640. Additional information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site at http://www.fda.gov/AdvisoryCommittees/default.htm.

FOR FURTHER INFORMATION CONTACT: For questions relating to participation in the selection process: Kimberly Hamilton, Advisory Committee Oversight and Management Staff (ACOMS), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32. rm. 5117, Silver Spring, MD 20993-0002, 301-796-8224, email: kimberly.hamilton@fda.hhs.gov.

For questions relating to specific advisory committees or panels, contact the appropriate Contact Person listed in table 1 in the SUPPLEMENTARY INFORMATION section.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting that any consumer organizations interested in participating in the selection of voting and/or nonvoting consumer representatives to serve on its advisory committees or panels notify FDA in writing (see table 1 for Contact Person).

Table 1.--Advisory Committee Contacts

Contact Person	Committee/Panel
Janie Kim Center for Biologics Evaluation and Research Food and Drug Administration 10903 New Hampshire Ave. Bldg. 71, rm. 6129 Silver Spring, MD 20993-0002 Phone: 301-796-9016 Email: Janie.Kim@fda.hhs.gov	Cellular, Tissue and Gene Therapies
Philip Bautista Center for Drugs Evaluation and Research Food and Drug Administration 10903 New Hampshire Ave. Bldg. 31, rm. 2410 Silver Spring, MD 20993-0002 Phone: 301-796-9006 Email: Philip.Bautista@fda.hhs.gov	Drug Safety and Risk Management Advisory Committee
Natasha Facey Center for Devices and Radiological Health Food and Drug Administration 10903 New Hampshire Ave. Bldg. 66, rm. 1552 Silver Spring, MD 20993-0002 Phone: 301-796-5290 Email: Natasha.Facey@fda.hhs.gov	Immunology Devices Panel

Terri Crescenzi Office of the Commissioner Food and Drug Administration 10903 New Hampshire Ave. Bldg. 32, rm. 5152 Silver Spring, MD 20993-0002 Phone: 301-796-8646 Email: Terrie.Crescenzi@fda.hhs.gov	Pediatrics Advisory Committee
Donna Mendrick National Center for Toxicological Research Food and Drug Administration 10903 New Hampshire Ave. Bldg. 32, rm. 2208 Silver Spring, MD 20993-0002 Phone: 301-796-8892 Email: Donna.Mendrick@fda.hhs.gov	Science Advisory Board to National Center for Toxicological Research (NCTR)
Bryan Emery Center for Biologics Evaluation and Research Food and Drug Administration 10903 New Hampshire Ave. Bldg. 71, rm. 6132 Silver Spring, MD 20993-0002 Phone: 240-402-8054 Email: Bryan.Emery@fda.hhs.gov	Transmissible Spongiform Encephalopathies Advisory Committee
Sujata Vijh Center for Biologics Evaluation and Research Food and Drug Administration 10903 New Hampshire Ave. Bldg. 71, rm. 6128 Silver Spring, MD 20993-0002 Phone: 240-402-7107 Email: Sujata.Vijh@fda.hhs.gov	Vaccines and Related Biological Products Advisory Committee

FDA is requesting nominations for voting and/or nonvoting consumer representatives for the vacancies listed in table 2.

Table 2.--Committee Descriptions, Type of Consumer Representative Vacancy and Approximate Date Needed

Committee/Panel/ Areas of Expertise Needed	Type of Vacancy	Approximate Date Needed
Cellular, Tissue and Gene Therapies Advisory Committee--Knowledgeable in the fields of cellular therapies, tissue transplantation, gene transfer therapies and xenotransplantation (biostatistics, bioethics, hematology/oncology, human tissues and transplantation, reproductive medicine, general medicine and various medical specialties including surgery and oncology, immunology, virology, molecular biology, cell biology, developmental biology, tumor biology, biochemistry, rDNA technology, nuclear medicine, gene therapy, infectious diseases, and cellular kinetics.	1-Voting	3/31/2016
Drug Safety and Risk Management Advisory Committee--Knowledgeable in risk communication, risk management, drug safety, medical, behavioral, and biological sciences as they apply to risk management, and drug abuse.	1-Voting	Immediately
Immunology Devices Panel--Persons with experience in medical, surgical, or clinical oncology, internal medicine, clinical immunology, allergy, molecular diagnostics, or clinical laboratory medicine.	1-Non-Voting	2/28/2016
Pediatrics Advisory Committee--Knowledgeable in pediatric research, pediatric subspecialties, statistics, and/or biomedical ethics. The core of voting members shall also include one representative from a pediatric health organization and one representative from a relevant patient or patient-family organization and may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.	1-Voting	Immediately
Science Advisory Board to the NCTR--Knowledgeable in the fields related to toxicological research.	1-Voting	Immediately
Transmissible Spongiform Encephalopathies Advisory Committee--Knowledgeable in the fields of clinical and administrative medicine, hematology, virology, neurovirology, neurology, infectious diseases, immunology, transfusion medicine, surgery, internal medicine, biochemistry, biostatistics, epidemiology, biological and physical sciences, sociology/ethics, and other related professions.	1-Voting	Immediately
Vaccines and Related Biological Products Advisory Committee--Knowledgeable in the fields of	1-Voting	Immediately

Table 2.--Committee Descriptions, Type of Consumer Representative Vacancy and Approximate Date Needed

immunology, molecular biology, rDNA, virology, bacteriology, epidemiology or biostatistics, allergy, preventive medicine, infectious diseases, pediatrics, microbiology, and biochemistry.		

II. Functions and General Description of the Committee Duties

A. Cellular, Tissue, and Gene Therapies Advisory Committee

Reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies and xenotransplantation products which are intended for transplantation, implantation, infusion and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair or replacement of tissues for various conditions, as well as considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products.

B. Drug Safety and Risk Management Advisory Committee

Risk management, risk communication, and quantitative evaluation of spontaneous reports for drugs for human use and for any other product for which the FDA has regulatory responsibility. Scientific and medical evaluation of all information gathered by the Department of Health and Human Service (DHHS) and the Department of Justice with regard to safety, efficacy, and abuse potential of drugs or other substances, and recommends actions to be taken by DHHS with regard to the marketing, investigation, and control of such drugs or other substances.

C. Certain Panels of the Medical Devices Advisory Committee

The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation. The

panels engage in a number of activities to fulfill the functions the Federal Food, Drug, and Cosmetic Act (the act) envisions for device advisory panels. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, advises the Commissioner of Food and Drugs (the Commissioner) regarding recommended classification or reclassification of devices into one of three regulatory categories, advises on any possible risks to health associated with the use of devices, advises on formulation of product development protocols, reviews premarket approval applications for medical devices, reviews guidelines and guidance documents, recommends exemption of certain devices from the application of portions of the act, advises on the necessity to ban a device, and responds to requests from the Agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices. With the exception of the Medical Devices Dispute Resolution Panel, each panel, according to its specialty area, may also make appropriate recommendations to the Commissioner on issues relating to the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices. The Dental Products Panel also functions at times as a dental drug panel. The functions of the dental drug panel are to evaluate and recommend whether various prescription drug products should be changed to over-the-counter status and to evaluate data and make recommendations concerning the approval of new dental drug products for human use.

D. Pediatrics Advisory Committee

The Committee advises and makes recommendations to the Commissioner of Food and Drugs regarding: (1) Pediatric research; (2) identification of research priorities related to pediatric therapeutics and the need for additional treatments of specific pediatric diseases or conditions; (3) the ethics, design, and analysis of clinical trials related to pediatric

therapeutics; (4) pediatric labeling disputes; (5) pediatric labeling changes; (6) adverse event reports for drugs granted pediatric exclusivity and any safety issues that may occur; (7) any other pediatric issue or pediatric labeling dispute involving FDA regulated products; (8) research involving children as subjects; and (9) any other matter involving pediatrics for which FDA has regulatory responsibility. The Committee also advises and makes recommendations to the Secretary directly or to the Secretary through the Commissioner on research involving children as subjects that is conducted or supported by DHHS.

E. Science Advisory Board to the National Center for Toxicological Research

Reviews and advises the Agency on the establishment, implementation and evaluation of the research programs and regulatory responsibilities as it relates to NCTR. The Board will also provide an extra-agency review in ensuring that the research programs at NCTR are scientifically sound and pertinent.

F. Transmissible Spongiform Encephalopathies Advisory Committee

Reviews and evaluates available scientific data concerning the safety of products which may be at risk for transmission of spongiform encephalopathies having an impact on the public health, as well as considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products.

G. Vaccines and Related Biological Products Advisory Committee

Reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are intended for use in the prevention, treatment, or diagnosis of human diseases, as well as considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products.

III. Criteria for Members

Persons nominated for membership as consumer representatives on committees or panels should meet the following criteria: (1) Demonstrate ties to consumer and community-based organizations, (2) be able to analyze technical data, (3) understand research design, (4) discuss benefits and risks, and (5) evaluate the safety and efficacy of products under review. The consumer representative should be able to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committees on scientific issues that affect consumers.

IV. Selection Procedures

Selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and public advocacy groups. These organizations recommend nominees for the Agency's selection. Representatives from the consumer health branches of Federal, State, and local governments also may participate in the selection process. Any consumer organization interested in participating in the selection of an appropriate voting or nonvoting member to represent consumer interests should send a letter stating that interest to FDA (see ADDRESSES) within 30 days of publication of this document.

Within the subsequent 30 days, FDA will compile a list of consumer organizations that will participate in the selection process and will forward to each such organization a ballot listing at least two qualified nominees selected by the Agency based on the nominations received, together with each nominee's current curriculum vitae or resume. Ballots are to be filled out and returned to FDA within 30 days. The nominee

receiving the highest number of votes ordinarily will be selected to serve as the member representing consumer interests for that particular advisory committee or panel.

V. Nomination Procedures

Any interested person or organization may nominate one or more qualified persons to represent consumer interests on the Agency's advisory committees or panels. Self-nominations are also accepted. Nominations should include a cover letter and current curriculum vitae or résumé for each nominee, including a current business and/or home address, telephone number, and email address if available, and a list of consumer or community-based organizations for which the candidate can demonstrate active participation.

Nominations should also specify the advisory committee(s) or panel(s) for which the nominee is recommended. In addition, nominations should include confirmation that the nominee is aware of the nomination, unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest. Members will be invited to serve for terms up to 4 years.

FDA will review all nominations received within the specified timeframes and prepare a ballot containing the names of qualified nominees. Names not selected will remain on a list of eligible nominees and be reviewed periodically by FDA to determine continued interest. Upon selecting qualified nominees for the ballot, FDA will provide those consumer organizations that are participating in the selection process with the opportunity to vote on the listed nominees. Only organizations vote in the selection process. Persons who nominate themselves to serve as voting or nonvoting consumer representatives will not participate in the selection process.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: February 8, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016-03010 Filed: 2/12/2016 8:45 am; Publication Date: 2/16/2016]